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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,173	07/05/2007	Shinya Nagata	5553NA3-1	5331

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Jason H. Vick
Sheridan Ross, PC
Suite # 1200
1560 Broadway
Denver, CO 80202

EXAMINER	
SAIDI, AZADEH	
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3735	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,173	NAGATA ET AL.	
	Examiner	Art Unit	
	Anita Saidi	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/10/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

2. Claim 15 is objected to because of the following informalities: at line 4, "a plural" apparently should read --a plurality of--; at line 5, --the-- should be inserted before "vicinity" (both occurrences); and at line 5, "off" apparently should read --of--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the respiratory information measuring sensors" in line 3. There is insufficient antecedent basis for this limitation in the claim. The antecedent recites only a single such sensor. Therefore, it is unclear how many sensors the garment comprises.

Claim 16 recites the limitation "the respiratory information measuring sensors" in lines 5, 9 and 13. There is insufficient antecedent basis for this limitation in the claim. The antecedent recites only a single such sensor. Therefore, it is unclear how many sensors the garment comprises.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,551,252 to Sackner et al (Hereinafter "Sackner").

In reference to claim 12:

Sackner teaches a non-invasive monitoring of a plurality of physiological parameters, which comprises a nonconductive material garment (1 or 30) for measuring biological information (Abstract). The garment has elasticity (Col. 13, lines 35-47) so as to fit on the upper body of an examinee (Figs. 1 and 2). Respiratory sensors (band 4 and 6) are attached to the garment (Fig. 1). The sensors comprise conductive material (Col. 14, lines 33-50). The garment is capable of delivering electric information based on the variation of electric potential to a respiratory information analysis device (Col. 17, lines 7-18).

In reference to claim 13:

The sensors are disposed on one of a perimeter of the chest (4) and a perimeter of abdominal (6) in the garment. The electric resistance of the respiratory information measuring sensor varies with expansion and contraction of one of the length and cross-section of the conductive member in response to the examinee's breathing (Col. 8 and Col. 14).

In reference to claim 14:

The respiratory information measuring sensors are placed between two layers of non-conductive material, one covering a surface of the conductive member facing the body surface of the examinee and the other on the opposed surface (the sensors are embedded within the band, Col. 14, line 60-Col. 15, line 5 and Col. 19, lines 58-63).

In reference to claim 15:

The conductive member of the respiratory information measuring sensors is arranged at a plurality of positions at least including one of a position winding around vicinity of the chest (4 and Fig. 1) of the examinee and a position winding around vicinity of the abdominal of the examinee (6 and Fig. 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 16-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackner in view of US 2004/0133123 to Leonhardt et al (Hereinafter "Leonhardt") and US 5,439,002 to Narimatsu et al (Hereinafter "Narimatsu").

In reference to claim 16:

Sackner teaches:

The ambulatory system comprises a hand held device for processing the acquired data (17 of Sackner). The hand held device comprises a respiratory electric information acquisition means (the cable 2, 14 and 15 of Sackner) for acquiring information on electricity delivered from the respiratory information measuring sensors (Fig. 1 of Sackner). Electric information comparison means are used (microprocessor 33 of Sackner) for comparing a plurality of the acquired electric information (Col. 20, line 64-Col. 21, line 3 of Sackner). Respiratory information analysis means (microprocessor 33 of Sacker) are used for judging a variation cycle of the electric information detected with the respiratory information measuring sensors selected by the electric information selection means which analyze respiratory information in accordance with the variation cycle (Col. 17, lines 20-40 and Col. 20, lines 23-40 and lines 58-65). Respiratory information output means (display 45 of Sackner) are used for outputting

respiratory information data in accordance with the analyzed respiratory information.

However, Sackner fails to teach that:

A plurality of electric sensors are used for monitoring respiratory signals. An electric information comparison and selection means is used for comparing the acquired information and for selecting the information from the sensors by detecting the larger amplitude as the electric potential information to be used as the output of the respiratory information. The larger amplitude is selected by performing an optimization on the collected signals.

Leonhardt teaches:

The use of multiple sensors for measuring respiratory activity of a subject (Abstract and Fig. 1 of Leonhardt).

It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used multiple sensors similar to the ones taught by Leonhardt in the ambulatory device of Sackner in order to monitor changes in the ventilation system of a subject with a higher accuracy and a better grasp on the respiratory function for each lung.

However, the combination of Sackner and Leonhardt fails to teach that:

An electric information comparison and selection means is used for comparing the acquired information and for selecting the information from the sensors by detecting the larger amplitude as the electric potential

information to be used as the output of the respiratory information. The larger amplitude is selected by performing an optimization on the collected signals.

Narimatsu teaches:

A blood pressure monitoring system which comprises a CPU (34 of Narimatsu) that measures pulse wave signals collected from the sensor (22). The CPU determines an optimum chamber pressure, HDPS, as an optimum pressing force to be applied to the pulse wave sensor (20 of Narimatsu), and calculates from each of the thus obtained pulse wave signals (SM of Narimatsu), the amplitude of each of successive pulses corresponding to heart beats of the subject, and selects as the optimum PS element (31a of Narimatsu) one of the thirty PS elements (30 of Narimatsu) which has detected a maximum pulse having the greatest amplitude of all the calculated amplitudes (Col. 6, lines 17-25 of Narimatsu).

It is well known in the art to perform an optimization amongst the signals collected in order to choose the best result, when monitoring physiological activities of a subject. Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used the optimization technique similar to the one taught by Narimatsu, in the ambulatory system of Sackner as modified by Leonhardt in order to select the optimum signal between all the data received from multiple sensors. This will

improve the accuracy of the system in case one or two of the sensors are not performing at their peak.

In reference to claims 17 and 22:

Sackner teaches:

A respiratory information analysis device and method of controlling a respiratory information analysis device, which comprises a computer readable medium recording a program for programming a computer as a cardiogram analysis device. Sackner teaches a non-invasive monitoring of a plurality of physiological parameters using a nonconductive material garment (1 or 30) for measuring biological information (Abstract). The garment has elasticity (Col. 13, lines 35-47) so as to fit on the upper body of an examinee (Figs. 1 and 2). Respiratory sensors (band 4 and 6) are attached to the garment (Fig. 1). The sensors comprise conductive material (Col. 14, lines 33-50). The garment is capable of delivering electric information based on the variation of electric potential to a respiratory information analysis device (Col. 17, lines 7-18). The ambulatory system comprises a hand held device for processing the acquired data (17 of Sackner). The hand held device comprises a respiratory electric information acquisition means (the cable 2, 14 and 15 of Sackner) for acquiring information on electricity delivered from the respiratory information measuring sensors (Fig. 1 of Sackner). Electric information

comparison means (microprocessor 33 of Sackner) are used for comparing a plurality of the acquired electric information (Col. 20, line 64-Col. 21, line 3 of Sackner). Respiratory information analysis means (microprocessor 33 of Sacker) are used for judging a variation cycle of the electric information detected with the respiratory information measuring sensors selected by the electric information selection means which analyze respiratory information in accordance with the variation cycle (Col. 17, lines 20-40 and Col. 20, lines 23-40 and lines 58-65). The respiratory information is outputted via a display unit (PDA and display 45 of Sackner).

However, Sackner fails to teach that:

A plurality of electric sensors are used for monitoring respiratory signals. An electric information comparison and selection means is used for comparing the acquired information and for selecting the information from the sensors by detecting the larger amplitude as the electric potential information to be used as the output of the respiratory information. The larger amplitude is selected by performing an optimization on the collected signals.

Leonhardt teaches:

The use of multiple sensors for measuring respiratory activity of a subject (Abstract and Fig. 1 of Leonhardt).

It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used multiple sensors similar to the ones taught by Leonhardt in the ambulatory device of Sackner in order to monitor changes in the ventilation system of a subject with a higher accuracy and a better grasp on the respiratory function for each lung.

However, the combination of Sackner and Leonhardt fails to teach that:

> An electric information comparison and selection means is used for comparing the acquired information and for selecting the information from the sensors by detecting the larger amplitude as the electric potential information to be used as the output of the respiratory information. The larger amplitude is selected by performing an optimization on the collected signals.

Narimatsu teaches:

> A blood pressure monitoring system which comprises a CPU (34 of Narimatsu) that measures pulse wave signals collected from the sensor (22). The CPU determines an optimum chamber pressure, HDPS, as an optimum pressing force to be applied to the pulse wave sensor (20 of Narimatsu), and calculates from each of the thus obtained pulse wave signals (SM of Narimatsu), the amplitude of each of successive pulses corresponding to heart beats of the subject, and selects as the optimum PS element (31a of Narimatsu) one of the thirty PS elements (30 of Narimatsu) which has detected a maximum pulse having the greatest

amplitude of all the calculated amplitudes (Col. 6, lines 17-25 of Narimatsu).

It is well known in the art to perform an optimization amongst the signals collected in order to choose the best result, when monitoring physiological activities of a subject. Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used the optimization technique similar to the one taught by Narimatsu, in the ambulatory system of Sackner as modified by Leonhardt in order to select the optimum signal between all the data received from multiple sensors. This will improve the accuracy of the system in case one or two of the sensors are not performing at their peak.

4. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackner in view of Leonhardt and Narimatsu as applied to claim 17 above, and further in view of US 2006/0100536 to Nagai et al (Hereinafter "Nagai").

In reference to claims 19 and 20:

Sackner, as modified by Leonhardt and Narimatsu, teaches all of the claim limitations; see the rejection of claim 17 above.

Sackner also teaches that the combination of RR intervals of the ECG measurements from the sensor (26 of Sackner) and the tidal breath waveform from the respiratory inductive plethysmographic sensors (20 and 21 of

Sackner) can be used for detecting arrhythmia and other respiratory and cardiac diseases (Col. 22, lines 53-60 of Sackner).

However Sackner, Leonhardt and Narimatsu fail to teach that:

> The system further acquires information on an R-wave height cycle related to a variation cycle of R-wave height information of cardiogram based on electric potentials acquired from a cardiogram electrode or that the system also acquires information on amplitude of the electric information and information on R-wave height amplitude related to amplitude of the R-wave height information and selects one of the electric information and the R-wave height information in accordance with a comparison of the electric information and the R-wave height information and analyzes respiratory information in accordance with the selected cycle information.

Nagai teaches:

> A graph display processing device and method that facilitates easy viewing of data with periodicity (Abstract of Nagai). The R-wave is monitored and based on the amplitude data it is determined whether or not a magnitude of the amplitude in the cycle fits a predetermined amplitude criterion. If it is determined that the magnitude of the amplitude does not fit the amplitude criterion, the display magnification is changed in the direction of the variation components in the output region (¶ [0038] of Nagai). The graph display processing device can display the graph in an appropriate size while taking into account amplitude data based on an R-

wave height (R potential) of the electrocardiographic waveform (¶ [0043] of Nagai).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have acquired and considered the R-wave amplitude and height, as taught by Nagai in the ambulatory system of Sackner, as modified by Leonhardt and Narimatsu, in order to be able to display the cardiac signal and any changes occurring during each cycle.

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sackner in view of Leonhardt and Narimatsu and Nagai as applied to claim 19 above, and further in view of US 5,704,351 to Mortara et al (Hereinafter "Mortara").

In reference to claim 21:

Sackner, as modified by Leonhardt, Narimatsu and Nagai, teaches all of the claim limitations; see the rejection of claim 19 above.

However, Sackner, Leonhardt, Narimatsu and Nagai fail to teach that:

The respiratory information analysis means display one of a position of the cardiogram electrode and a position of the respiratory information measuring sensor detecting the selected information correspondingly with one of a diagram of the biological information measuring garment and a diagram of the examinee's body.

Mortara teaches:

A digital telemetry transmitter for transmitting eight channels of diagnostic quality electrocardiographic data (Abstract of Mortara). The signals from each channel are displayed on the display device (27 and Fig. 1 of Mortara). A diagram of the patient with the sensor position is displayed on the screen (35 and 37 of Mortara). A fault at one of electrodes 18, for example, a disconnected electrode, causes a dot.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have displayed a diagram of the patient and all the sensors attached, similar to the teachings of Mortara in the ambulatory system of Sackner as modified by Leonhardt, Narimatsu and Nagai, in order to view the position and performance of each sensor and to detect any malfunction of each sensor.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,588,425 to Sackner et al discloses a method and apparatus for discriminating between valid and artifactual pulse waveforms. US 2003/0045806 to Brydon discloses a respiratory analysis system. US 2005/0240087 to Keenan et al discloses a method and system for processing data from ambulatory physiological monitoring. US 7,245,956 to Matthews et al discloses an unobtrusive measurement system for bioelectrical signals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is (571)270-3001. The examiner can normally be reached on Monday-Friday 9:30 am - 6:00 pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/A. S./
Examiner, Art Unit 3735
3/26/2008